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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,591	03/08/2002	Shinji Yamamori	Q68895	1085

65565 7590 01/28/2008

SUGHRUE-265550
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EXAMINER	
MOSS, KERI A	
ART UNIT	**PAPER NUMBER**
1797	
MAIL DATE	**DELIVERY MODE**
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/092,591	**Applicant(s)** YAMAMORI ET AL.	
	Examiner Keri A. Moss	**Art Unit** 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9,10,13-15,17,18,20,21,24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,9,10,13-15,17,18,20,21,24 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2007 has been entered.

2. Claims 1,3-5,9-10,13-15,17-18,20-21,24,26-32 are pending.

Response to Amendment

The previous rejections under section 102 over Yamamori, Fertig, and O'Neil as well as the previous rejections under section 103 over O'Toole and Passaro have been withdrawn. New grounds of rejection under section 103 over these same references have been raised.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims **1, 3, 5, 9-10, 13, and 17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamori et al. (USP 5,957,127) in view of Dietz (USP 5,005,571). Yamamori discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a

light-emitting light element (part 3) operable to emit light, a light-receiving element (Fig. 12, part below 6) adapted to receive the light emitted from the light-receiving element, a support member (part 2) supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body (at the esophagus or also parts 1a and 1b may be placed just below the nostrils), a respiratory flow path (either part 2e or 1e) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the nostrils of the living body and a first guide member (part 1a or 1b) adapted to introduce the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (Fig. 9) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (part 1 a or 1b) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path. The sensor may also comprise an oxygen mask (Fig. 3). The sensor also comprises an airway case (part 1) adapted to be located below the nostrils of the living body and having a pair of openings opposing each other and a pair of transparent thin films (parts 1d and 1c) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis through the openings (Figs. 9, 11 and 12, part 2). The first guide member is removably engaged with the support member (Fig. 9). The airway case comprises a pair of openings opposing each other (parts 1d and 1c), a respiratory flow path

extending between the openings, a pair of transparent thin films (inherent) respectively and a pair of supporting members (Fig. 12 parts supporting parts 3 and part 6) so as to oppose each other on a single optical axis through the openings.

Regarding claim 10, the respiratory flow path (including part 1e) is part of the support member and forms an interior surface of the support member. And whereas the respiratory flow path and thus the support member is on the interior of the oxygen mask (Fig. 3), the support member is disposed on an interior surface of the oxygen mask.

Yamamori does not disclose the use of a mask with ear straps nor a guide member with nasal prongs. Dietz discloses a nasal cannula with prongs used with or without a mouth nose mask (Figs 1 and 2; column 2 lines 32-43) for the purpose of sensing inhalation. The nasal cannula uses ear straps adapted to be hooked around ears for holding the cannula below the nostrils (Figs. 1 and 2). The advantage of using a nasal cannula for sensing is that a nasal cannula is more efficient in detecting nasal inhalation when breathing occurs through a nose (column 2 lines 32-38). The mouth nose mask makes it possible for the nasal cannula to function when the mask user's upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 44-47). An additional advantage of using the mask and nasal cannula in combination is that the mouth nose mask allows fluids being delivered by a nasal cannula to enter the mask and be inhaled orally when upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 54-57). It would have been obvious for one of ordinary skill in the art to modify the disclosure of Yamamori by adding a nasal cannula with ear straps alone or in combination with a

mask to the disclosed sensing device in order to gain the advantages of more efficient detection, of ensuring fluid delivery and detection takes place when a patient's nasal passageways are blocked and to ensure fluid delivery through the mouth when the patient's nasal passageways are blocked.

5. Claims **1, 3, 5, 9, 13-14 and 17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fertig et al. (USP 5,095,900) in view of Dietz (USP 5,005,571). Fertig discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a light-emitting light element (Fig. 1 part 16) operable to emit light, a light-receiving element (Fig. 1 part 22) adapted to receive the light emitted from the light-receiving element, a support member (Fig. 1 part 14) supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body, a respiratory flow path (Fig. 1 labeled II) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the nostrils of the living body (esophagus) and a first guide member (Fig. 4, part 10) capable of introducing the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (the back end of the open area of part 12, labeled II) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (Fig. 4 part 9) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path.

The sensor also comprises an airway case (Fig. 4 part 2) adapted be located below the nostrils of the living body (i.e. at the esophagus) and having a pair of openings opposing each other (Fig. 4 parts 6 and 8) and a pair of transparent thin films (Fig. 4 parts 6 and 8) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis through the openings (Figs 9, 11 and 12, part 2). The first guide member is removably engaged with the support member. The thin films are anti-fogging films (column 3 lines 18-27).

6. Fertig does not disclose the use of a mask with ear straps nor a guide member with nasal prongs. Dietz discloses a nasal cannula with prongs used with or without a mouth nose mask (Figs 1 and 2; column 2 lines 32-43) for the purpose of sensing inhalation. The nasal cannula uses ear straps adapted to be hooked around ears for holding the cannula below the nostrils (Figs. 1 and 2). The advantage of using a nasal cannula for sensing is that a nasal cannula is more efficient in detecting nasal inhalation when breathing occurs through a nose (column 2 lines 32-38). The mouth nose mask makes it possible for the nasal cannula to function when the mask user's upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 44-47). An additional advantage of using the mask and nasal cannula in combination is that the mouth nose mask allows fluids being delivered by a nasal cannula to enter the mask and be inhaled orally when upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 54-57). It would have been obvious for one of ordinary skill in the art to modify the disclosure of Fertig by adding a nasal

cannula with ear straps alone or in combination with a mask to the disclosed sensing device in order to gain the advantages of more efficient detection, of ensuring fluid delivery and detection takes place when a patient's nasal passageways are blocked and to ensure fluid delivery through the mouth when the patient's nasal passageways are blocked.

7. Claims **1, 3, 5, 9, 13-18, 20-21, 24-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (USP 5,957,127) in view of Dietz (USP 5,005,571). O'Neil discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a light-emitting light element (Fig. 2 part 11) operable to emit light, a light-receiving element (Fig. 2 part 13) adapted to receive the light emitted from the light-receiving element, a support member (Fig. 2 part 5) supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body, a respiratory flow path (Fig. 2 between parts 7 and 9) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the nostrils of the living body and a first guide member (Fig. 1 part 21) adapted to introduce the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (Fig. 2 parts 7 and 9) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (Fig. 1 part 23) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path. The sensor also comprises an

airway case (Figs 1 and 3, part 4) adapted to be located below the nostrils of the living body and having a pair of openings (parts 17) opposing each other and a pair of transparent thin films (column 5 lines 59-62)) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis through the openings (Figs 9, 11 and 12, part 2). The first guide member is removably engaged with the support member. The airway case comprises a pair of supporting members (parts located at 7 and 9) each of which is adapted to removably engage with one of the light-emitting element and the light-receiving element such that they are supported so as to oppose each other on a single optical axis through the openings (Fig. 2). The thin films are anti-fogging films (column 5 lines 59-62).

8. O'Neil does not disclose the use of a mask with ear straps nor a guide member with nasal prongs. Dietz discloses a nasal cannula with prongs used with or without a mouth nose mask (Figs 1 and 2; column 2 lines 32-43) for the purpose of sensing inhalation. The nasal cannula uses ear straps adapted to be hooked around ears for holding the cannula below the nostrils (Figs. 1 and 2). The advantage of using a nasal cannula for sensing is that a nasal cannula is more efficient in detecting nasal inhalation when breathing occurs through a nose (column 2 lines 32-38). The mouth nose mask makes it possible for the nasal cannula to function when the mask user's upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 44-47). An additional advantage of using the mask and nasal cannula in combination is that the mouth nose mask allows fluids being delivered by a nasal cannula to enter the

mask and be inhaled orally when upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 54-57). It would have been obvious for one of ordinary skill in the art to modify the disclosures of Yamamori, Fertig or O'Neil by adding a nasal cannula with ear straps alone or in combination with a mask to the disclosed sensing device in order to gain the advantages of more efficient detection, of ensuring fluid delivery and detection takes place when a patient's nasal passageways are blocked and to ensure fluid delivery through the mouth when the patient's nasal passageways are blocked.

9. Claims **1, 3-5, 9-10, 13, 15, 17-18, 20-21, 24, 26-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Toole (USP 6,379,312) in view of Passaro et al. (USP 4,423,739) and further in view of Yamamori, supra. O'Toole discloses an apparatus for sensing carbon dioxide while delivering oxygen to the patient. The device includes nasal tubes (first guide member) as well as oral tubes or oral apertures for receiving a breath sample (second guide member). The body of the device functions as a mask. The nasal tubes attach to a conventional cannula, which provides oxygen. The conventional cannula contains ear straps. The nasal tubes for a Y-shape (Figs 2 and 3 – dotted outline within the body 10). The mask is substantially parallel with the face of the living body.

While O'Toole does not teach using the cord for sending signals as an ear strap, it would have been obvious for one of ordinary skill in the art to move the cord from part

26 from near the patient's mouth to strap around the ear in order to avoid getting it in the patient's or doctor's way.

O'Toole teaches attaching an end tidal carbon dioxide gas analyzer to the mask apparatus, but does not teach the specifics of the sensor (column 3 lines 62-66). Passaro teaches an end tidal carbon dioxide gas analyzer. The analyzer contains a light-emitting element (Fig. 1 part 11), a light-receiving element (Fig. 1 part 21), a support member supporting the light-emitting element (Fig. 1 parts 13 and 15) and the light receiving element (Fig. 1 part 20), an airway case (part 17) with a respiratory flow path (parts 25 and 27) and a pair of transparent thin films sealing the openings (windows 29).

Passaro does not disclose details of the device used for delivering a patient's expired air into the disclosed sensor; however, Passaro does teach that the patient's breath is conveyed to the inlet of the sample cell from the patient's airway by a suitable mask connection (column 2 lines 34-37). O'Toole provides that mask connection.

O'Toole and Passaro do not expressly disclose a sensor whereby the sensor is adapted to be located between the nostrils and the mouth. Yamamori discloses such a sensor as part of a device incorporating the flow-through method of breath sampling. In Figure 3, Yamamori discloses a device adapted to perform the flow through method by guiding the respiratory gas from the nostrils to the respiratory flow path formed in the support member located between the nostrils and the mouth. The advantages of a device adapted to perform the flow through method over one adapted to perform the gas sampling method are well known among those with ordinary skill in the art (see

Applicant's Amendment Remarks filed October 30, 2007, pages 16-17). The concentration profiles in the gas sampling method are somewhat distorted and the results are delayed due to the length of the gas sampling tube. One of ordinary skill in the art would have recognized the advantages of integrating the sensor of Passaro into the mask of O'Toole to form a single unit like that of Yamamori in order to gain the advantages of a compact device that does not provide distorted results and that does not provide delayed results. In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) ("the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice"). A compact device would also require fewer parts by eliminating the need for long sampling tube from the patient's mouth to the analyzer. Therefore, it would have been obvious for one of ordinary skill in the art to combine O'Toole, Passaro and Yamamori to improve the devices of O'Toole and Passaro in a known way and gain the advantages of instant and accurate results.

Response to Arguments

10. Applicant's arguments, see Applicant's Amendment, filed October 30, 2007, with respect to the rejection(s) under section 102 due to the failure of the references to teach nasal prongs have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of section 103 under Yamamori, Fertig and O'Neil in view of Dietz, supra.

11. Applicant's arguments with respect to claims **1, 3-5, 8-10, 13, 15, 17-21, 24-28** under O'Toole in view of Passaro have been considered but are moot in view of the new ground(s) of rejection in view of O'Toole, Passaro and Yamamori.

12. Applicants argue that Yamamori fails to disclose a support member disposed on an interior surface of the oxygen mask since detecting portion 2 is disposed on the monitor body. However, applicants overlooked part 1e, which is disposed on an interior surface of the oxygen mask and therefore does meet the limitations of claim 10.

13. Applicants argue that the O'Neil reference does not teach a sensor having a size adapted to be located between nostrils and a mouth of the living body. However, the airway adapter parts 4 and 23, like the airway adapters of Yamamori and Fertig, are clearly capable of being used directly at the mouth of the patient. The sensor of O'Neil is attached to the airway adapter and is thus capable of being located between nostrils and mouth of the living body. Applicants have provided no evidence that the size is not capable of being located between the nostrils and the mouth. In the absence of evidence to the contrary, the Examiner interprets O'Neil as being capable of being located between the nostrils and mouth of a living body.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keri A. Moss
Examiner
Art Unit 1797

KAM 1/22/08

LYLE A. ALEXANDER
PRIMARY EXAMINER